

Comparison of reusable and single-use ureteroscopes for the treatment of medium-sized stones in the lower calyx: A prospective randomized study

Reusable and single-use ureteroscopes

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Abstract

Aim: Single-use flexible ureteroscopes (fURSs) were developed as an alternative in order to eliminate the cost disadvantages of reusable ureteroscopes in the treatment of kidney stones. The objective of this study was to compare single-use and reusable fURSs for the treatment of medium-sized stones in the lower calyx.

Material and Methods: The data of patients who underwent retrograde intrarenal surgery (RIRS) for medium-sized stones (10-20) mm in the renal pelvis were analyzed prospectively. The patients were divided into two groups according to the fURS model used during the operation. Uscope PU3022™ (Pusen®, China) was used as single-use fURS, and Flex X2™ (Karl Storz®, Germany) as reusable. Failed RIRS following Double-J stent insertion was considered as the first session and each RIRS operation as a separate session.

Results: The mean operation time was 20 minutes shorter in the reusable fURS group (53±17.4 vs 73.1±21.6, $p < 0.001$). The mean number of sessions was less in the reusable fURS group (1.3±0.46 vs. 1.6±0.59, $p = 0.014$). The stone-free rate was similar in both groups (77.5% vs. 72.5, $p = 0.606$).

Discussion: The success rates of reusable and single-use ureteroscopes in the treatment of medium-sized stones in the lower calyx were similar. However, the mean operation time was shorter and the number of sessions was less in the reusable ureteroscopy arm.

Keywords

Single-use; Ureteroscope; Reusable ureteroscope; RIRS; Medium sized

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Introduction

Retrograde intrarenal surgery (RIRS), also known as flexible ureterorenoscopy (fURS), is a less invasive procedure with fewer complications compared to other procedures and is effective for medium-sized kidney stones (10–20 mm) even with complex anatomy and patients using anticoagulants [1]. With technological advancements, ureteroscopes used for these procedures gained the ability to allow irrigation and to actively deflect, which provides them with treatment features [2]. Over time, the fURS has evolved and has become an indispensable tool in renal stone treatment together with improvements in laser lithotripsy [3]. Stone-free rates (SFRs) of up to 90% have been provided with RIRS carried out using fURS [4]. With the widespread use of reusable fURSs, high initial and repair costs as well as sterilization and reprocessing expenditures became an apparent burden [5]. With the development in digital technologies, single-use fURS are marketed and used today, with test results comparable in terms of scope characteristics and vision [6]. However, these devices are relatively new in the market and therefore, currently, there are only limited comparative data in the literature about single-use fURS and reusable fURS in terms of clinical efficiency, costs and safety. The first digital single-use fURS, Lithovue™ (Boston Scientific USA) was reported to be equivalent to standard reusable scopes in terms of performance and safety [7]. The UscopePU3022™ digital single-use fURS (Zhuhai Pusen Medical Technology Company Limited, China) has recently been introduced as a potential competitor to Lithovue™, with the claim of assuring comparable clinical performance, but at a lower cost [8].

Marchini et al. compared UscopePU3022 and Lithovue fURSs with the reusable Flex-X2 scope, but in this study, technical features were investigated rather than clinical performance [9].

Presentation

The objective of this study was to compare single-use with reusable fURS in terms of overall clinical performance in the treatment of medium-sized (10–20 mm) stones in lower calyx under similar conditions.

Material and Methods

A total of 80 patients who presented to our hospital and were treated with RIRS due to 10–20 mm sized stones in the lower calyx between May 2018 and December 2018 were included in the study. The patients were divided into two groups according to the fURS model used during the operation. Reusable fURS (7.5 Fr) was used in the first group, and single-use fURS (9.5 Fr) in the second group. Patients' demographics such as age and gender, stone size and surface area, operation time, number of sessions, success and complications were recorded. Patients with stones localized other than lower calyx, a history of prior stone surgery or extracorporeal shock-wave lithotripsy (SWL) or RIRS for significant residual stone, pediatric patients, those with comorbidities such as diabetes mellitus, hypertension, and ischemic heart disease, patients on anticoagulants, and those with prior nephrostomy or double-j stent due to infection were excluded from the study. The study protocol was approved by the local ethics committee (Decision No: 2021/99). Written informed consent was obtained from all patients before operation. The study was conducted in compliance with the

ethical principles of the Declaration of Helsinki.

Surgical Technique

Urine culture was taken in addition to routine laboratory examinations, and the operation was performed when urine culture became negative. Preoperative 1 g ceftriaxone was administered intravenously. An attempt was made to insert access sheath in all patients in the first session. If the access sheath could not be inserted during the first attempt with single-use fURS, the operation was discontinued considering that the device rigidity was not sufficient to provide access over the guide wire, a double-j (DJ) stent was inserted and operation was performed 2 weeks later. Whereas in the reusable fURS, access was attempted through the guide wire, even if the access sheath could not be placed. The Zebra guide wire™ (Boston Scientific®, USA) was inserted into the ureter with reusable fURS, and the intramural ureter was dilated with reusable fURS up to the mid ureter, then the access sheath was tried over the guide wire. UscopePU3022™ (Pusen®, China) was used as single-use fURS, and Flex X2™ (Karl Storz®, Germany) as reusable. Access sheaths of Flexor-Regular (R; 9.5/11.5 Fr, Cook Medical, USA) and Flexor Ureteral Access Sheath Hydrophilic Coating (R; 10.7/12.7 Fr, Cook Medical, USA) were used in reusable fURS and single-use fURS, respectively. DJ stent was inserted into all patients at the end of the first procedure.

Evaluation of Outcomes and Complications

A failed RIRS following DJ insertion was considered as the first session and each RIRS operation as a separate session, while removal of DJ stents was not counted as a session. Complete SFR status or clinically insignificant stones (≤ 3 mm) on non-contrast CT three months after the last operation was considered successful. Operation time was defined as the duration from the insertion of fURS through urethral meatus up to DJ stent placement. All operations were carried out by a single urologist experienced in fURS. The stone surface area was determined by computed tomography by measuring the length of the three dimensions.

Statistical Analysis

Data obtained in the study were analyzed using the SPSS for Windows version 21.0 statistical software. The normality of the data was tested using the Kolmogorov-Smirnov method. Comparison between the groups was made using the Mann-Whitney U test for continuous variables and the Chi-square test for categorical variables. Continuous variables were expressed as mean \pm standard deviation, min and max descriptive values, and categorical values as the number and percentage $p < 0.05$ values were statistically significant.

Results

Eighty patients were included in the study with 47 of whom were males (58.8%) and 33 (41.2%) females. The mean age of the patients was 46.4 ± 13.1 (25–75) years. At the end of three months, 60 patients were stone-free (75%), of whom, 31 (77.5%) were in the reusable fURS and 29 (72.5%) in the single-use fURS group. No statistically significant difference was found between the two groups in terms of SFR ($p = 0.606$). Five patients developed complications with two being in the reusable and three in the single-use fURS group. The operation was terminated in three patients due to ureteral injury, and in

Table 1. Demographic and clinical features of the patients

	Reusable (Flex X2®)	Single-use (PU3022®)	p value
Number	40	40	
Mean age (year) ±sd	49.4±16.2	43.3±13.3	0.45
Gender (f/m)	19/21	14/26	0.256
Side (right/left)	20/20	17/23	0.501
Mean Stone surface area (mm ²)±sd	121.8±64.4	132.8±52.8	0.267

Table 2. Treatment outcomes of the patients (*: p- value is significance under 0.05).

	Reusable (FlexX2®)	Single-use (PU3022®)	p value
Mean operation time (min)± sd	53±17.4	73.1±21.6	<0.001*
Additional session due to failed initial access (%)	3 (7.5%)	11 (27.5%)	0.005*
Additional session for residual stone	9 (22.5%)	11 (27.5%)	0.317
Mean number of sessions±sd	1.3±0.46	1.6±0.59	0.014*
Complete stone- free status (%)	31 (77.5%)	29 (72.5%)	0.606
Complication (%)	2 (5%)	3 (7.5%)	0.644

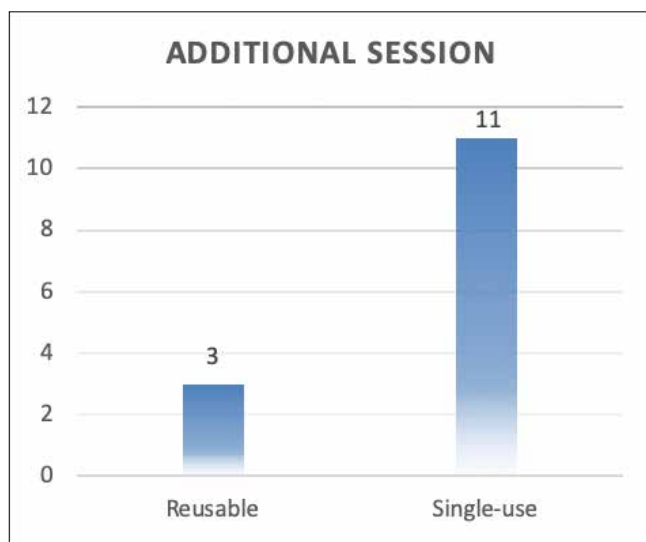


Figure 1. Comparison of the number of the additional sessions due to access failure.

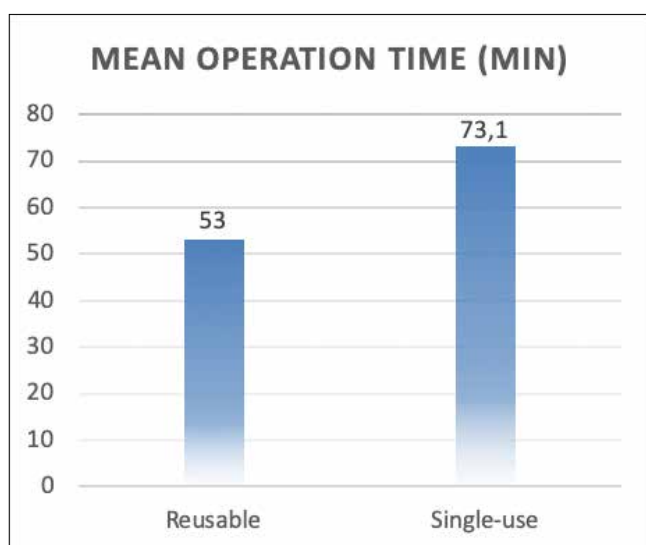


Figure 2. Comparison of the mean operation time.

two patients because of bleeding. These five patients had no additional intervention except for DJ stent placement, and the stones were removed in the second session. The mean stone surface areas were similar between both groups (p =0.267) (Table 1).

In the reusable group, 12 patients underwent the second session, three of which were due to failed access in the first intervention and nine for residual stone. A total of 22 additional sessions were performed in the single-use fURS group: two sessions in 20 patients and three sessions in two patients; of these 22 additional sessions, eleven were performed due to residual stone, and the remaining eleven since the first access was unsuccessful. The need for additional sessions due to failure of the first attempt was significantly lower in the reusable fURS group compared to the single-use fURS group (p=0.005) (Figure 1).

Additional session for residual stone was similar in both groups (22.5% vs. 27.5%, p = 0.317). The successful access rate in the first session was higher in the reusable fURS group (92.5% vs 72.5%, p = 0.03). The mean operation time was 20 minutes shorter in the reusable fURS group (53±17.4 vs 73.1±21.6, p< 0.001) (Figure 2).

The mean number of sessions was less in the reusable fURS group (1.3±0.46 vs. 1.6±0.59, p= 0.014). The stone-free rate was similar in both groups (77.5% vs. 72.5%, p = 0.606). Treatment outcomes of both groups are given in Table 2.

Discussion

Flexible ureteroscopy has been performed with increasing frequency over the last two decades, with stone-free rates equal to the PCNL for stone sizes ≤ 2 cm [10, 11]. With this method, SFR was achieved by 95% in previous reports regardless of kidney stone location. The Clinical Research Office of the Endourological Society (CROES) study has prospectively collected data from more than 10,000 patients. The authors of this study found SFRs of 90% and 80% for stones <10 mm and <15 mm in size, respectively, after a single session of RIRS [12]. As to data with Polyscope™, Bader et al. performed an in vitro and clinical assessment with this single-use fURS, the field of view and image quality were comparable to reusable fURS [13]. During clinical evaluation, they described the facility to insert this ureteroscope over a guidewire or through an access sheath, with an 89.5% SFRs in 40 laser lithotripsy procedures (mean stone size 1 cm), mean operation time of 26 minutes and no intraoperative complications. In another study, Gu et al. reported their experience with Polyscope™, in which SFR was 89.5% in 86 patients (median stone size 1.23 cm) with nine patients requiring secondary procedures [14]. In our study, the overall SFR was 75%, while this rate was 77.5% in the reusable fURS group and 72.5% in the single-use fURS group. This rate was higher in the reusable group, although the difference was not statistically significant (p=0.606).

To avoid the costs associated with the repair and sterilization of conventional reusable fURS, many institutions are now using single-use alternatives. Reduced costs at initial purchase of equipment and reliability are advantages of single-use fURS. Furthermore, single-use fURS has comparable SFRs with reusable fURS for treating nephrolithiasis [15]. A recent

retrospective study incorporated LithoVue™ data from 159 cases across 14 care centers to evaluate the clinical efficacy of this single-use fURS [16]. Investigators reported a 96.8% first-treatment success rate in terms of ability to access stone, structure, and upper urinary tract urothelial carcinoma lesion.

In our study, the operation time was 53±17.4 minutes in the reusable fURS and 73.1±21.6 minutes in the single-use fURS group ($p<0.001$). Similarly, Salvado et al. found that the mean operation time was 76.4 minutes with single-use fURS in middle-sized stones [10]. Usawachintachit et al. found that single-use LithoVue™ fURS cases were, on average, 10-15 minutes shorter and resulted in almost a quarter of an hour less total time in the operating room compared to reusable fURS [7]. Single-use fURS displays more success in complex lower calyceal stones, as SFR following single-use fURS was slightly higher than rates reported in RIRS studies with reusable fURS [17]. A possible explanation for the higher SFR in lower pole stones could be the fact that when using single-use equipment, the surgeon may be less concerned about damaging the fURS and, therefore, could maximally deflect the scope without fear [18]. Salvado et al. inserted DJ stent preoperatively in 10 patients with medium-sized stones, which means 45.5% additional operative session due to failed access. The clinical data observed in this series does not differ from the previous results traditionally obtained with other reusable devices, however, the study did not compare outcomes with reusable equipment under similar conditions [10].

Usawachintachit et al. reported that single-use fURS was associated with a statistically significantly decreased complication rate compared to the use of reusable scopes. Their reusable fURS group experienced a three-fold increased rate of complications compared to single-use fURS [7]. Whereas in our study, no significant difference was found between the reusable and single-use groups in terms of complication rates ($p=0.644$). Our complication rates are lower than those of the previous studies [19, 20]. Mager et al. prospectively compared 68 reusable flexible uretero-renaloscopies (Flex-X2S, Flex-XC, Karl Storz) and 68 single-use fURSs (LithoVue, Boston Scientific) [21]. Comparing clinical outcomes of reusable vs. single-use instruments revealed no significant difference for overall success rates (81 vs. 87%), stone-free rates (82 vs. 85%), mean operation time (76.2 vs. 76.8 min), radiation exposure time (3.83 vs. 3.93 minutes) and complication rates (7 vs. 17%) ($p > 0.05$). The above cited studies compared clinical performance of different fURS devices regarding overall urinary stone clearance. However, no study was found in the literature comparing reusable and single-use fURSs in the treatment of lower calyx stones. To the best of our knowledge, the present study is the first trial evaluating both types of instruments in the treatment of lower calyx stone. In our series, SFRs, operation time and preoperative DJ stent placement were 72.5% vs 77.5%, 73.1 vs. 53 minutes ($p<0.001$) and 27.5% vs. 7.5% ($p=0.005$), respectively for the single use fURS vs. reusable fURS, which seem to be in contrast to recently published studies. We found that additional session number and operation time was statistically significantly higher in the single-use fURS group. On the other hand, larger access sheath and instrument sizes requires an initial DJ insertion in many cases to assure dilation

for the following single-use fURS session. The second issue is that the quickly worsening visibility during a fURS session prolongs the operation time. A prospective cohort study carried out with the UscopePU3022™ across 11 centers in 2017 suggested that this assumption may be true. The authors concluded that the UscopePU3022™ performed well with regards to maneuverability, deflection and limb fatigue and appears to be comparable to standard fURS; however, poor visibility is a concern for UscopePU3022™ with receiving a low overall performance rating compared to standard fURS. The image was reported to be too dark, especially at the periphery, which was evident when navigating the renal pelvis. In order to improve vision, we attached a triple port to the single-use fURS to suction turbid fluid in the renal pelvis and therefore, a certain time elapsed when manipulating the port from inflow to outflow and vice versa. Finally, in our study the mean number of sessions was significantly lower in the reusable group ($p=0.014$). In general, looking at our results, reusable fURS seem advantageous compared to single-use fURS in terms of treatment performance with shorter operation time and fewer additional sessions. Given fluoroscopy exposure with fURS, reusable devices seem to decrease this advantage with shorter operation time. However, considering cost factor reusable fURS brings both initial and repair costs increasingly with the widespread use of TIRS operations worldwide. We believe that technological advancement will eliminate the cost disadvantage of relatively new single-use fURSs, making that devices more practicable in the treatment of middle-sized kidney stones.

Limitations

There are also limitations to our study. We could not measure fluoroscopy time and stone density, and could not perform a cost analysis among comparative clinical data. However, being the first study comparing these two devices is the strength of our study.

Conclusions

The success rates of reusable and single-use ureteroscopes in the treatment of medium sized stones in lower calyx were comparable. However, the mean operation time was shorter and the number of sessions was less with the reusable ureteroscopy arm. The routine clinical use of single-use fURSs is still a matter of investigation and discussion worldwide; however, their real potential and economic advantages remain to be elucidated with comprehensive studies. Thanks to advancements, similar results can be obtained if single-use fURS vision achieves better visual quality and smaller calibrations.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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